

U.S. Patent Application Serial No. 09/147,052
Response filed January 10, 2005
Reply to OA dated August 26, 2004

REMARKS

Claims 25, 26, 32, 33, 39-41 and 43-46 are pending in this application, with claims 45 and 46 currently withdrawn from consideration. Claims 20-24, 27-31 and 34-38 have been canceled herein without prejudice or disclaimer. Claims 25, 26, 32 and 33 have been amended herein. No new matter has been added by this amendment. Support for the claim amendments is discussed below.

Regarding paragraph no. 2 of the Office action.

Withdrawn claims 31 and 34-38 have been canceled without prejudice or disclaimer. Withdrawn claims 45 and 46 are still pending.

Claims 20-30, 32, 33 and 39-44 ([sic], claim 42 is canceled) are rejected under 35 U.S.C. §103(a) as being unpatentable over Saitoh [or Saito] et al., (WO 94/23019) and Yoshida et al., (Virology 1994, vol. 200, pp. 484-493) and further in view of Nazerian et al. (EP 520,753). (Office action paragraph no. 5)

The rejection is moot for claims 20-24 and 27-30, which have been canceled without prejudice or disclaimer.

The rejection of claims 25, 26, 32, 33, 39-41 and 43-44 is overcome by the amendments to the claims. In independent claims 25, 26, 32 and 33, "Herpesvirus outer membrane protein" has

been amended to --herpes virus gB protein--. Support for this amendment may be found in the specification on page 8, lines 22-27, which lists gB as a specific example of an outer membrane protein of herpes simplex virus that can be used in the invention.

Summary of the rejection

In the rejection, the Examiner cites Saitoh for teaching novel polypeptides that exhibit the antigenicity of *M. gallisepticum*, and states that Saitoh teaches an antigenic protein corresponding to amino acids 64-456 of SEQ ID NO: 2 of the present application. The Examiner also cites Saitoh as teaching that a fused polypeptide “comprising the polypeptide and connected to the N-terminus thereof, a signal membrane anchor of a type II outer-membrane polypeptide of a virus that infects birds,” quoting the Abstract of the reference.

The Examiner cites Yoshida et al. for teaching the glycoprotein B genes of Marek’s Disease Virus Serotypes 2 and 3.

The Examiner states at the bottom of page 5 of the Office action that Saitoh and Yoshida do not teach a signal polypeptide with amino acids 1-672 of SEQ ID NO: 4, that is, the outer membrane gB protein derived from MDV (see specification on page 10, lines 22-22). The Examiner cites Nazerian for discussing Marek’s disease and teaching a “signal polypeptide encompassing an identical sequence to both 1-63 of SEQ ID NO: 1 and 1-672 of SEQ ID NO: 4” of the present invention.

The Examiner states that it would have been obvious “to incorporate well known sequences, useful in the same field of art, that creates the same immunity as taught by Nazerian et al.”

Non-obviousness of the amended claims over the cited references

The amended claims recite a recombinant Avipox virus or vaccine containing the combination of **an antigenic protein with a signal polypeptide of herpes virus gB protein, wherein the signal polypeptide is ligated with the antigenic protein at the N terminus thereof such that the antigenic protein is secreted extracellularly.** The claims have been amended to specifically recite the **herpes virus gB protein.**

Applicant asserts that this combination enables the recombinant Avipox virus or vaccine to be extremely effective in *in vivo* vaccination, and that this represents an **unexpected result** over the combined references.

In this regard, Examples 1 to 3 of the present specification show the actual construction of the recombinant fowl pox viruses (FPV) 40K-C and 40K-S having a DNA encoding Mycoplasma gallisepticum antigenic protein (TTM-1) with a signal polypeptide of gB gene of Marek's disease virus.

Further, Example 5 of the specification demonstrates that the recombinant viruses 40K-C and 40K-S induced highly effectively antibodies against Mycoplasma gallisepticum. Moreover, Example 6 demonstrates the *in vivo* highly effective vaccination of the 40K-C and 40K-S.

Applicant refers to the Rule 132 Declaration of Mr. Shuji Saitoh (executed June 21, 2000) which was submitted to the USPTO along with an Amendment on June 27, 2000.

As shown in the Declaration, chickens inoculated with the recombinant viruses of Saito (fNZ7929-67, fNZ27929-66 and fNZ2929XM1) exhibited approximately the same average lesion

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score as non-inoculated chicken *in vivo* (see the Table at page 3 of the Declaration). The method for calculating the average lesion scores in the test of the Declaration is the same as in the test of Table 3 of Example 6 of the present specification.

In particular, the line "None" in the Table of the Declaration is the same as the "None" in Table 3 of the present specification. Thus, the test results in the Declaration confirm that the recombinant viruses of Saito are not effective in the *in vivo* vaccination against Mycoplasma infection.

That is, the claimed recombinant Avipox virus or vaccine is much more effective in the *in vivo* vaccination than the invention of Saito. Applicant further argues that the effectiveness of the presently claimed invention **would not be expected** based on the teachings of the cited references.

Saito merely teaches that a signal membrane anchor of HN gene of New Castle disease virus (NDV) is connected to an antigenic gene of Mycoplasma gallisepticum.

Saito and the other references (i.e., Yoshida and Nazerian) teach nothing whatsoever of the combination of **an antigenic protein with a signal polypeptide of herpes virus gB protein, wherein the signal polypeptide is ligated with the antigenic protein at the N terminus thereof such that the antigenic protein is secreted extracellularly**, as required by the present invention. As such, the observed vaccination effectiveness associated with the presently claimed combination would not be predicted based on these references.

Applicant therefore submits that the claimed invention provides unexpected results over the cited references, commensurate with the scope of the claims. Claims 25-30, 32, 33, 39-41 and 43-44, are therefore novel and non-obvious over Saitoh [or Saito] et al., (WO 94/23019), Yoshida et al.,

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(Virology 1994, vol. 200, pp. 484-493) and Nazerian et al. (EP 520,753), taken separately or in combination.

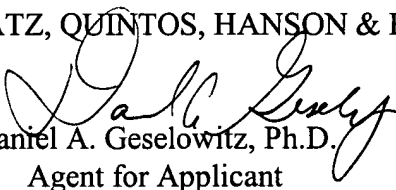
In view of the aforementioned amendments and accompanying remarks, the claims, as amended, are in condition for allowance, which action, at an early date, is requested.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact Applicant's undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, Applicant respectfully petitions for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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